Application Number: 09/405, 43

Docket: /6599

a drive for moving the piston comprising a drive for supplying power, a drive member and a driven member only contacting the piston, wherein the drive member and driven member are telescopically coupled.

#### **REMARKS**

The above amendments and these remarks are submitted in response to the Office Action of August 28, 2002. In the Action, the Examiner objected to the drawings and specification. Claims 1-14 and 17-20 were rejected as being indefinite, and claims 1-20 were rejected as anticipated by U.S. Patent 5,514,097 (Knauer).

## Objection to the Drawings

The drawings were objected to on the basis of an assertion that the "reaction member" of claim 6 is not shown. However, the Examiner's attention is respectfully directed to Figure 13, which depicts the reaction member 6, i.e., a feed screw, and to the specification describing Figures 13 and 14 (at page 12, the paragraph beginning "The propelling device as shown in Figs. 13 and 14 ...").

### Objection to the Specification

The specification has been amended to include an abstract, and section headings have been added.

## Rejection under 35 U.S.C. § 112

Claims 1-14 and 17-20 were rejected under 35 U.S.C. § 112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These rejections concerned insufficient antecedent basis and have been addressed by the above amendments.

#### Rejection under 35 U.S.C. § 102

Claims 1-20 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 5,514,097 (Knauer). This rejection is respectfully traversed for the following reasons.

Each of the independent claims of the present application (claims 1, 15 and 16), including new claims 21 and 23, recite that the propelling device is operably coupled to the piston only by contact. The piston, in turn, engages the plunger and moves the plunger inside the medicine container.

In contrast, the Knauer discloses a push rod locking mechanism 626. (Knauer, Figures 6A and 6B, and column 13, lines 57-58, column 15, lines 6-30, and column 16, lines 57-62.) As explained in Knauer, the locking mechanism is required so "the plurality of assemblies move together" to deliver a dose. (Knauer, column 3, lines 25-39.) This is critical because Knauer is directed to an injection apparatus designed to push a plurality of assemblies, including the needle, forward with enough force so

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that the needle penetrates the patient's skin and the apparatus dispenses a dose of medicine in the tissue, thus sparing the patient the step of introducing an exposed needle into his or her own tissue.

The advantage derived from the present invention over the Knauer device is that the propelling device and the container are separately accommodated in a common housing so that either the container, the propelling device or both can be exchanged simply since a mechanical connection between the propelling device, the piston and/or to the container does not first have to be released.

For at least the proceeding reasons, the independent claims are not anticipated by Knauer, nor are the dependent claims. The § 102 rejection based on Knauer is unfounded and should be withdrawn.

Conclusion

The above amendment adds additional claims (3 total, including 2 independent), generating claim fees in the amount of \$186.00. In addition, a petition for an extension of time to respond, from November 28, 2002 until February 28, 2003, is enclosed herewith. Two checks, one in the amount of \$186.00 and one in the amount of \$930.00, are enclosed to cover the respective fees. The Office is also hereby anthorized to charge any fee deficiency associated with this communication or the accompanying petition to Deposit Account 04-1420.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Marked-up Version Showing Changes."

In view of the above amendments and preceding remarks, it is urged respectfully that the rejection of the claims be reconsidered and withdrawn, and that claims 1-23 be allowed. If the Examiner believes that any issues remain unresolved, he is invited to telephone the undersigned to expedite allowance

Date: 12003

Respectfully submitted,

D.,,

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## MARKED-UP VERSION SHOWING CHANGES

#### IN THE SPECIFICATION

On page 1, after the title and before the first paragraph, please insert the heading
-- Background --;

On page 1, between the second and third paragraphs, please insert the heading -- Summary --;

On page 4, between the third and fourth paragraphs, before the sentence beginning "Although the invention primarily...", please insert the heading - <u>Brief Description of the Drawings</u> -;

On page 6, after the figure descriptions, before the sentence beginning "In the plan view of a...", please insert the heading — <u>Detailed Description</u>—.

#### IN THE ABSTRACT

Please insert the following in the Abstract.

An apparatus for administering a substance, including a housing, a piston, a container and a propelling device, the propelling device including a base element, a first shifting stage shiftable relative to the base element, and a second shifting stage shiftable relative to the base element and to the first shifting stage and slaving the first shifting stage, wherein the propelling device, container and piston are operably coupled to the housing and the first shifting stage is in contact with the piston.

#### IN THE CLAIMS

- 1. (Amended) An apparatus for administering a liquid medicament, comprising a housing, a piston, a container and a propelling device, said propelling device comprising:
- (a) a base element;
- (b) a first shifting stage being shiftable relative to said base element, said first shifting stage, on shifting, advances said piston in said container resulting in said liquid medicament being dispensed from said container in a metered manner; and
- (c) at least a second shifting stage being shiftable relative to said base element as well as relative to said first shifting stage in said advance direction of said piston and slaving said first shifting stage in its shifting movement in [the] an advance direction of said piston,
- (d) said first and said second shifting stages, when seen in said advance direction of said piston, overlap at least in part, wherein said propelling device and said container are accommodated and fixed



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in place in the housing, that said piston is held in said container and said first shifting stage is connected to said piston only by exerting contact pressure on said piston.

- 2. (Amended) The propelling device of claim 1, characterized in that said first and said second shifting stages are operably connected by a male thread and a female thread, forming a first spindle drive, [the] a rotational movement of which causes said first shifting stage to shift.
- 3. (Amended) The propelling device of claim 2, wherein said second shifting stage shifts as [the] a driven member of a second spindle drive.
- 8. (Amended) The propelling device of claim 1, wherein [the] an axis of rotation of said two spindle drives are in alignment.
- 10. (Amended) The propelling device of claim 3, wherein said first shifting stage is rotationally driven by [said] a drive member of said second spindle drive via a spur gear unit.
- 15. (Amended) A portable medicament administrating device comprising at least:
- (a) a housing,
- (b) a reservoir for a liquid medicament to be administered;
- (c) a piston which, by advancing, dispenses in a metered manner said liquid medicament to be administered from said reservoir; and
- (d) a propelling device operably coupled to said piston by contact only for advancing said piston.
- 17. (Amended) The apparatus according to claim 16, wherein said first and said second shifting stages are operably coupled by respective complementary threaded portions to form a first spindle drive, [the] a rotational movement of which causes said first shifting stage to shift.
- 18. (Amended) The apparatus according to claim 17, further comprising a second spindle drive, wherein said second shifting stage shifts as [the] a driven member of the second spindle drive.
- 19. (Amended) The apparatus according to claim 18, wherein said second shifting stage is substantially slaved in both rotation and shift by [a drive member of] said second spindle drive.

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Please add new claims 21-23 as follows:

21. (New) A propelling device for a device for administering a medicinal liquid, said device for administering comprising a housing, said propelling device comprising a drive module operably coupled to the housing and comprising:

a piston;

shifting stages comprising a first shifting stage and a second shifting stage, said first shifting stage operably coupled to said piston only by contacting said piston; and

a motor drive operably coupled to said shifting stages.

- 22. (New) The propelling device according to claim 21, wherein the shifting stages are telescopically coupled.
- 23. (New) A device for dispensing a medication comprising:

a housing;

a container having an outlet, the container received in the housing and containing the medication to be dispended through the outlet;

a piston; and

a drive for moving the piston comprising a drive for supplying power, a drive member and a driven member only contacting the piston, wherein the drive member and driven member are telescopically coupled.

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